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Conducting Human Research at the 59 MDW



Our unique vulnerable populations

- Basic Military Trainees (recruits)
- Technical Training Students
- Active Duty Personnel



How do we appoint an Ombudsman?

- Primary Reviewer(s) make recommendations regarding whether appropriate additional safeguards have been included in the study design to protect the rights and welfare of these subjects



- In addition, the reviewers recommend whether the study meets the requirements for a separate Ombudsman during recruitment
- The PI makes a recommendation
- The IRB votes to approve/disapprove the appointing of recommended individual(s) and can add any additional responsibilities they will require of the ombudsman (based on study design)

How do we train our Ombudsman

- Within 30 days of Ombudsman Appointment Letter, the appointee must complete the Biomedical Research module of CITI training for the protection of research subjects and notify the IRB upon completion and after the training is verified (and all other conditions are met). This is a requirement for the study approval.
- The PI will also provide additional training on the study's protocol.

Why is this important?

- Ensure there is no coercion or undue influence during the recruiting process
- The 59 MDW is committed to safeguarding the public trust, to complying with all policy and statutory requirements, and preserving trust in the integrity and quality of research carried out by the investigators at the 59 MDW.



59 Medical Wing



Protection of Vulnerable Population :

Ombudsman Program

Background

- The 59th Medical Wing (59MDW) is the first Department of Defense (DoD) and Air Force (AF) organization to obtain external national accreditation in human research subject protection
- Preparations included harmonizing DoD and AF specific regulations and policies with those from DHHS and the FDA. Our team developed a novel approach to implementing the "research monitor" and "research ombudsman" roles required by DoD to build upon protections already provided by the Common Rule, resulting in less burdensome and more practical policies and procedures.

59 MDW

- The 59MDW is the AF's premier healthcare, education, training, clinical research, and readiness Wing. The Chief Scientist (59MDW/ST) leads research by providing strategic direction, scientific expertise, project management, regulatory expertise, and fostering partnerships to advance modernization through innovative research, technologies and treatment interventions at 70 worldwide sites.
- The 59th Clinical Research Division is the largest AF Clinical Investigation Facility. It supports the Institutional Review Board and provides administrative, scientific, regulatory oversight and guidance to the Wing and 58 other institutions. 59MDW/ST spearheads the Human Research Protection Program (HRPP) on behalf of the 59MDW Commander and Institutional Official and chairs the HRPP Committee to ensure adherence to applicable laws, regulations, and ethical standards protecting the rights and welfare of our participants in the performance of highest-quality research.

DoD is different in our recruitment and consenting vulnerable populations and processes for ensuring their protection

DOD policy...

- DoDI 3216.02_AFI 40-402 describes when an Ombudsman is required, their training and duties
- An Ombudsman is defined in the DoDI 3216.02 Glossary as a person who acts as an impartial and objective advocate for human subjects participating in research.

What is an Ombudsman?

How does the IRB Reviewer determine the need for an Ombudsman?

The initial review of research worksheet has yes/no check boxes

How do our Ombudsman report issues

Provide ad hoc reports evaluating subject recruitment, enrollment and the consent process for subjects, groups or units, especially if coercion or undue influence is observed during the process.

The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense or its Components.

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What are our Ombudsman primary responsibilities

- An Ombudsman, in order to avoid the appearance of bias, must remain independent of the research study (e.g., can't participate or be involved in the study) and the research team conducting the human study.
- The Ombudsman shall not be associated in any way to the research and shall be present during the recruitment in order to monitor that the voluntary involvement of the Service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate
- The Ombudsman may also be the research monitor
- If the research has been determined to be NO greater than minimal risk and when recruitment occurs in a group setting, the decision to require the appointment of an Ombudsman should be based on the subject population, the consent process, and the recruitment strategy.
- If the research involves DoD civilians, the IRB will consider requiring an Ombudsman as above.

Consent Observation Process

Include process...

- In most cases to date, the Ombudsman has been appointed when research subjects have been recruited/consented in a group setting
- Senior leadership is not to be present during this process. Any military officer investigators performing the recruiting and consenting of subjects are required to be in civilian clothes.
- The Ombudsman also wears civilian clothes. This minimizes any potential coercion or undue influence due to officer and enlisted interactions during the recruiting and consenting process.
- The Ombudsman is highly encouraged to discuss the purpose and design of the study with the Principal Investigator or with other IRB members before performing their Ombudsman duties. This enhances the awareness of the Ombudsman as to what procedures require their close observance during the consenting process.
- If any signs of coercion or undue influence are observed, the Ombudsman is directed to address the matter immediately with the PI and provide an ad hoc report to the IRB clearly explaining the observed behavior of the research team and what immediate steps were taken to correct it.
- The Ombudsman has the authority to stop the recruiting/consenting process if the investigators continue with their unapproved actions. To date, we have not received any ad hoc report concerning coercion or undue influence being observed during any recruiting/consenting procedure.

59th Medical Wing Protection of Vulnerable Populations: Ombudsman Program

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The 59th Medical Wing (59 MDW) is the first Department of Defense (DoD) and U.S. Air Force (AF) organization to obtain external national accreditation in human research subject protection. In preparation for the Association for the Accreditation of Human Research Protection Program's (AAHRPP) visit, the 59 MDW HRPP harmonized DoD and AF-Specific regulations, DHHS and FDA regulations. The HRPP team developed a novel approach, the Ombudsman Program to implement the DOD requirements that build upon protections provided by the common rule.

The purpose of this poster is to 1) describe DoD vulnerable populations—BMT, students, active duty; 2) Describe ombudsman appointment/training and 3) explain the ombudsman responsibility/role.

The 37th Training Wing, Joint Base San Antonio-Lackland Air Force Base, Texas, is the largest training wing in the United States Air Force. The 37 TRW consists of five training groups and graduates more than 80,000 students annually. These five training groups encompass basic military training of all enlisted recruits entering the Air Force, Air Force Reserve and Air National Guard; and those attending technical training. This large student population is seen by many in the research community as a prime location to sample a young military population. The 59 MDW HRPP's Institutional Review Board (IRB) provides centralized administrative, scientific, regulatory oversight and guidance to 59 DoD and non-DoD institutions conducting research and when the research proposes to recruit/consent DoD vulnerable populations such as the aforementioned student population. The IRB makes a determination regarding whether special human protection mechanisms need to be put in place by the primary investigator. The Ombudsman appointment process is one such protection that can be put in place for protecting vulnerable populations.

A focus on protecting our most vulnerable populations is key to being a High Reliability Organization.

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